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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,494	08/17/2001	Trang T. Le	C-3320/1/US	5208

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/932,494	Applicant(s) LE ET AL.	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-13,18-25,28-41,46-53,62-83 and 86-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 10-13, 18-25, 28-41, 46-53, 62-83, 86-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Power of Attorney filed 09/22/03, Extension of Time, Amendment, and Request for Continued Examination filed 09/25/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/25/03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-13, 18-21, 23-25, 28-41, 46-49, 51-53, 62-83, 86-93, and 96-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Talley et al. US 5,760,068.

Mizumoto teaches quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and

additive agents (columns 13-19, claims 1-6). The drug used is in an amount of about 50%, and is not limited but include both analgesic and anti-inflammatory drugs (column 7). The method for preparing the tablet is disclosed in columns 12-13. The composition further comprises lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed in column 11.

Mizumoto does not specifically teach the claimed active agent to be a COX-2 inhibitor. However, COX-2 inhibitor is a well-known analgesic agent, particularly, anti-inflammatory, which can be used in conjunction with other analgesic agents.

Talley '068 teaches COX-2 such as celecoxib is a known anti-inflammatory agent. Thus it would have been obvious for one of ordinary skill in the art to prepare the quick-dissolved formulation of Mizumoto using the COX-2 inhibitor, such as celecoxib in view of the teachings of Talley, because the references teach the advantageous results in the use of a well-known anti-inflammatory agent.

The examiner notes that the cited references are silent as to the amounts of glidant, and wetting agent being claimed in claims 18-20 and 23-25. However, it is the position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Claims 1, 22, 42, 45, 50, 94, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Talley et al., in view of Jain et al. US 6,316,029.

Mizumoto and Talley are relied upon for the reason stated above. The references do not teach the specific glidant, and wetting agent.

Jain teaches process for preparing rapidly disintegrating solid oral dosage form comprising sodium lauryl sulfate and silicon dioxide (columns 8-9). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to use the sodium lauryl sulfate and silicon dioxide in view of the teaching of Jain to prepare the quick-dissolved formulation of Mizumoto since sodium lauryl sulfate and silicon dioxide are well known tabletting aids. The expected result would be compressed tablet having good hardness and dissolved quickly upon contact with fluid.

Response to Arguments

Applicant's arguments filed 09/25/03 have been fully considered but they are not persuasive.

The obviousness-type double patenting rejection has been withdrawn since the copending application No. 09/932,500 is abandoned.

Claims 1-3, 10-16, 18-21, 23-25, 28-44, 46-49, 51-53, 62-83, 86-93, and 96-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Talley et al. US 5,760,068.

Applicant argues that the prior art either alone or in combination, fails to teach or disclose the property of the claims, as well as, the function of the inhibitory step. Contrary to the applicant's argument, it is not necessary that the prior art teaches each and every property that accrues for the step of the process merely that the process steps be suggested. The prior art provides the step for inhibiting agglomeration. The step is provided when the prior art adding wetting agent. The step for "inhibiting agglomeration of the drug" is generic. It provides any means for inhibiting agglomeration. Furthermore the claimed step permits the adding of the inhibiting agent in any order.

Claims 1, 22, 42, 45, 50, 94, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Talley et al., in view of Jain et al. US 6,316,029.

Applicant argues that Jain fails to teach two elements, namely celecoxib and means to inhibit agglomeration. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Jain is cited in view of Mizumoto et al. and Talley et al. Furthermore, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested

in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Jain is relied upon solely for the teaching of sodium lauryl sulfate and silicon dioxide in a rapidly disintegrating solid oral dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600